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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,195	11/10/2003	Volker Buttcher	0147-0253p	5787
2292 7590 07/23/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
PAGE, BRENT T				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
07/23/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/705,195

**Applicant(s)**

BUTTCHEER ET AL.

**Examiner**

BRENT PAGE

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-14, 17-22, 24-31, 33, 35, 37-45, 47, 49 and 51-54 is/are rejected.
- 7) ☒ Claim(s) 23, 32, 34, 36, 46, 48 and 50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Response filed by Applicants on 03/10/2008 is hereby acknowledged. Due to a recent change in written description guidelines, a written description rejection is issued, accordingly, this action non-final.

Claims 1-54 are pending. Claims 6-9, and 15-16 are withdrawn. Claims 1-5, 10-14 and 17-54 are examined on the merits herein.

#### ***Claim Objections***

Claims 23, 32, 34, 36, 46, 48 and 50 are objected to because of the following informalities: The claims depend from rejected claims. The claims appear to be allowable if re-written in independent form. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-5, 10-14, and 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51 and -53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid that encodes a protein the sequence of which has a homology of at least 95% to the first 100 amino acids only of the amino acid sequence depicted in SEQ ID NO: 2.

In contrast, the specification only discloses SEQ ID NO:2 as a functioning branching enzyme from *Neisseria* and does not disclose any other embodiments that contain as little as 95% homology only to the first 100 amino acids of SEQ ID NO:2.

The specification does not disclose that only the first 100 amino acids are crucial to branching enzyme function, and the specification does not describe which features of the first 100 amino acids are critical for the invention so as to describe which amino acids may be added, substituted or deleted and still maintain the function of a branching enzyme. While the specification discusses peptide motifs, the specification does not describe which of the motifs are required for branching enzyme function, nor does the specification describe which motifs may be altered and the way in which they may be altered for the protein to retain its function as a branching enzyme.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties".

Given the claim breadth and lack of description and working examples as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in *Federal Register*/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

### ***Double Patenting***

Claims 1-5, 10-14, 17-22, 24-30, 37-44 and 51-54 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 6, 8, 11, 13, 15 and 17 of U.S. Patent No. 6566585. Although the conflicting claims are not identical, they are not patentably distinct from each other because the working examples that enable US Patent 6566585 are the embodiments claimed in the instant application, and are therefore disclosed in US Patent 6566585 as the exemplified embodiments of the invention.

Applicant's arguments filed 03/10/2008 have been fully considered but they are not persuasive.

Applicants urge that there would be no extension of patent term based on the earlier filing date of the instant application and further, that the claims of the instant application are not anticipated by the claims of US Patent 6566585 and that the patent disclosure may not be used as prior art.

This is not persuasive because the granting of more than one patent for the same invention is prohibited under patent law. In regard to anticipation, the claims of the issued patent render the instant claims obvious because the genus is narrow, i.e. a branching enzyme from a particular species; and in this case, the only disclosed embodiment of the issued patent is SEQ ID NO: 1, the same instantly claimed sequence, and as such, the instant claims are rendered obvious. Furthermore, the

transgenic plant cell comprising SEQ ID NO:1 is a species of the instant claims, and as such, additionally renders the instant claims obvious in light of the 6566585 patent.

For these reasons and the reasons of the office action mailed out on 10/10/2007, the claims are rejected for obvious-type double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1661

/Russell Kallis/

Primary Examiner, Art Unit 1638